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UTILITY

PATENT APPLICATION
TRANSMITTAL

Attorney Docket No.

JJI-49

First Named Inventor or Application Identifier

Larry B. Gray et al.

Express Mail Label No.

EL568230875US

APPLICATION ELEMENTS

MPEP Chapter 600 concerning utility patent application contents.

ADDRESS TO:

Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. ☒ Fee Transmittal Form (attached hereto in duplicate)
2. ☒ Specification [Total Pages 11]
(Preferred arrangement set forth below)
 - Descriptive Title of the Invention
 - Cross References to Related Applications
 - Statement Regarding Fed sponsored R&D
 - Reference to Microfiche Appendix
 - Background of the Invention
 - Brief Summary of the Invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
3. ☒ Drawing(s) (35 USC 113) [Total Sheets 7]
4. Oath or Declaration
 - a. ☐ Newly executed (original or copy)
 - b. ☐ Unexecuted original
 - c. ☒ Copy from a prior application (37 CFR 1.63(d))
(for continuation/divisional check boxes 5 and 16)
 - i. ☐ Deletion of Inventor(s)
Signed statement attached deleting inventor(s) named in the prior application, see 37 CFR 1.63(d)(2) and 1.33(b).
5. ☐ Incorporation by Reference
(useable if Box 4c is checked)
The entire disclosure of the prior application, from which a copy of the oath or declaration is supplied under Box 4c, is considered as being part of the disclosure of the accompanying application and is hereby incorporated by reference therein.

6. ☐ Microfiche Computer Program (Appendix)
7. Nucleotide and/or Amino Acid Sequence Submission (if applicable, all necessary)
 - a. ☐ Computer Readable Copy
 - b. ☐ Paper Copy (identical to computer copy)
 - c. ☐ Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

8. ☐ Assignment Papers (cover sheet & document(s))
9. ☐ 37 CFR 3.73(b) Statement
(when there is an assignee) ☐ Power of Attorney
10. ☐ English Translation Document (if applicable)
11. ☒ Information Disclosure Statement
(IDS)/PTO-1449 ☐ Copies of IDS Citations
12. ☒ Preliminary Amendment
13. ☒ Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
14. ☐ Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. ☒ Other: Abstract
Associate Power of Attorney

16. ☒ If a CONTINUING APPLICATION, check appropriate box and supply the requisite information:
Amend the specification by inserting before the first line: -- This is a ☒ Continuation ☐ Divisional
☐ Continuation-in-Part (CIP) of prior application No.: 09/232,544, filed January 18, 1999. --
17. For this divisional application, please cancel original Claims of the prior application before calculating the filing fee.

18. CORRESPONDENCE ADDRESS

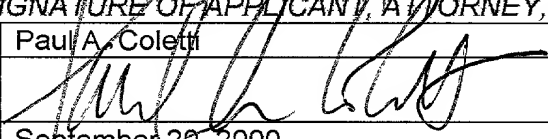
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19. TELEPHONE CONTACT

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Telephone: (732) 524-2815 Fax: (732) 524-2808

19. SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED

NAME	Paul A. Coletti	Reg. No. 32019
SIGNATURE		
DATE	September 20, 2000	

FEE TRANSMITTAL	<i>Complete if Known</i>	
	Application Number	
	Filing Date	
	First Named Inventor	Larry B. Gray et al.
	Group Art Unit	
	Examiner Name	
	Attorney Docket Number	JJI-49

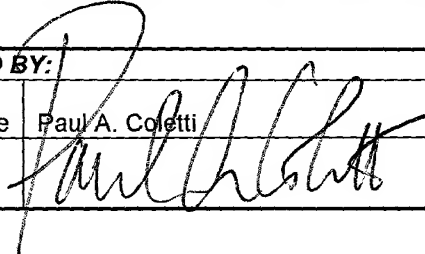
FEE CALCULATION

CLAIMS AS FILED

(1)	(2)	(3)	(4)	(5)
FOR:	NUMBER FILED	NUMBER EXTRA	RATE	BASIC FEE \$690.00
TOTAL CLAIMS	4 - 20 =	0	x 18.00	\$ 0.00
INDEPENDENT CLAIMS	4 - 3 =	1	x 78.00	\$ 78.00
MULTIPLE DEPENDENT CLAIMS	<input type="checkbox"/>	N/A	\$260.00	
			TOTAL FEES	\$ 768.00

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	Date: 9/20/00	

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Larry B. Gray, Ann Eckert, Todd Chelak, and
Robert Tumarkin

For : AXIALLY FLEXIBLE STENT

Express Mail Certificate

"Express Mail" mailing number: EL568230875US

Date of Deposit: September 20, 2000

I hereby certify that this complete continuation application, including specification pages, claims, formal drawings, Preliminary Amendment, Information Disclosure Statement, and an Declaration and Power of Attorney, is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

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(Signature of person mailing paper or fee)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Larry B. Gray et al.

Serial No. : Art Unit:

Filed : Examiner:

For : AXIALLY FLEXIBLE STENT

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United States Postal Service as first class mail in an envelope addressed
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(Date)

Paul A. Coletti

Name of applicant, assignee, or Registered Representative

(Signature)

September 20, 2000

(Date of Signature)

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

Please amend the above-captioned application as follows:

IN THE DRAWINGS:

Please find a new set of formal drawings provided herein.

IN THE SPECIFICATION:

On page 10, lines 18 and 22, please change "10" to -- 10' --.

On page 11, line 23, after "link" please insert -- as in 7 or 8 --.

On page 12, line 18, please delete "6" in the first instance and insert
-- 5 --.

On page 13, lines 5, 9, 14, 17, 19 and 27, please delete "10".

On page 14, lines 10, 11, 14, 18, 26 and 30, please delete "10".

On page 15, lines 5, 10, 17, 22, 24, 32 and 33, please delete "10".

On page 16, lines 5, 11, 16, 17 and 18, please delete "10".

On page 16, line 34, please delete "16", and insert -- 14 --.

On page 17, line 15, please delete "103" and insert -- 102 --.

IN THE CLAIMS:

Please cancel claims 1-19.

Please add the following claims:

20. A stent having first and second ends with an intermediate section therebetween, and a longitudinal axis with an unexpanded configuration comprising: circumferentially spaced, longitudinally disposed struts; wherein each strut defines a wave along said longitudinal axis; and

links for maintaining the struts along said circumference in a tubular structure, wherein the struts and links define an expandable structure having axial flexibility in said unexpanded configuration.

21. A stent having first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis, and both an unexpanded and expanded configuration comprising:

(a) a plurality of longitudinally disposed struts, wherein each strut defines a wave along the longitudinal axis; the spatial frequency of the wave associated with each of the struts being different in a first end

region lying proximate to one of said ends in comparison to the spatial frequency of the wave in the intermediate section; and

(b) a plurality of links for maintaining the struts in a tubular structure;

wherein said frequency is greater in said first region.

22. A stent having first and second ends with an intermediate section therebetween, and a longitudinal axis, and both an unexpanded and expanded configuration comprising:

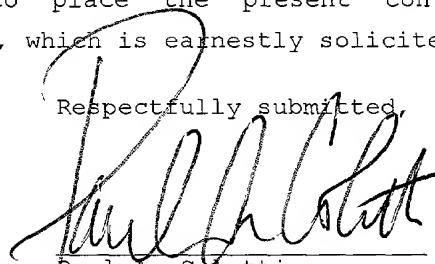
said unexpanded configuration comprises a plurality of longitudinally disposed wave-shaped struts; and

a plurality of circumferential links for maintaining the struts in a tubular structure, wherein each strut is connected at a plurality of locations by a link to an adjacent strut, each link being axially displaced from any circumferentially adjacent link.

REMARKS

This amendment is believed to place the present continuation application in condition for allowance, which is earnestly solicited.

Respectfully submitted,



Paul A. Coletti
Attorney for Applicant(s)
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September 20, 2000

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

AXIALLY FLEXIBLE STENT

5

Cross Reference

This application claims the benefit of the earlier filing dates of US provisional applications: 60/010,686 filed January 26, 1996; 60/017,479 filed April 26, 1996; 60/017,415 filed May 8, 1996; 60/024,110, filed August 16, 1996 incorporated herein by reference.

10

Technical Field

The present invention relates to a stent having axial flexibility and resilience in its expanded form.

15

Background Art

A stent is commonly used as a tubular structure left inside the lumen of a duct to relieve an obstruction. Commonly, stents are inserted into the lumen in a non expanded form and are then expanded autonomously (Tihon et al. (1994) U.S. Patent No. 5,356,423) or with the aid of a second device *in situ*. Although a number of designs have been reported, these designs have suffered from a number of limitations. These include; restrictions on the dimension of the stent (Cardon et al. 1995 U.S. Patent No 5,383,892). Cardon et al. describes a stent that has rigid ends (8mm) and a flexible median part of 7-21mm. This device is formed of multiple parts and is not continuously flexible along the longitudinal axis. Another stent design that has rigid segments and flexible segments has been described by Pinchasik et al. US Patent 5,449,373 (1995).

25

Other stents are described as longitudinally flexible (Lau et al.(1995) U.S. Patent No. 5,421,955 also EP application 540290 A2, A3) but consist of a plurality of cylindrical elements connected by flexible members. This design has at least one important disadvantage, for example, according to this design, protruding edges occur when the stent is flexed around a curve raising the possibility of inadvertent retention of the stent on plaque deposited on arterial walls. This may cause the stent to embolize or move out of position and further cause damage

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to the interior lining of healthy vessels. (see Figure 1(a) below).

Thus, stents known in the art, which may be expanded by balloon angioplasty, generally compromise axial flexibility to permit expansion and provide overall structural integrity.

5

Summary of The Invention

The present invention overcomes some perceived shortcomings of prior art stents by providing a stent with axial flexibility. In a preferred embodiment, the stent has a first end and a second end with an intermediate section between the two ends. The stent further has a longitudinal axis and comprises a plurality of longitudinally disposed bands, wherein each band
10 defines a generally continuous wave along a line segment parallel to the longitudinal axis. A plurality of links maintains the bands in a tubular structure. In a further embodiment of the invention, each longitudinally disposed band of the stent is connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band. The wave associated with each of the bands has approximately the same fundamental spatial frequency in the intermediate section,
15 and the bands are so disposed that the waves associated with them are spatially aligned so as to be generally in phase with one another. The spatially aligned bands are connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band.

In particular, at each one of a first group of common axial positions, there is a circumferential link between each of a first set of adjacent pairs of bands.

20 At each one of a second group of common axial positions, there is a circumferential link between each of a second set of adjacent rows of bands, wherein, along the longitudinal axis, a common axial position occurs alternately in the first group and in the second group, and the first and second sets are selected so that a given band is linked to a neighboring band at only one of the first and second groups of common axial positions.

25 In a preferred embodiment of the invention, the spatial frequency of the wave associated with each of the bands is decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section. In a further embodiment of the invention, the spatial frequency of the bands in the first and second end regions is decreased by 20% compared with
30 the spatial frequency of the bands in the intermediate section. The first end region may be

located between the first end and a set of circumferential links lying closest to the first end and the second end region lies between the second end and a set of circumferential links lying closest to the second end. The widths of corresponding sections of the bands in these end regions, measured in a circumferential direction, are greater in the first and second end regions than in the intermediate section. Each band includes a terminus at each of the first and second ends and the adjacent pairs of bands are joined at their termini to form a closed loop.

In a further embodiment of the invention, a stent is provided that has first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis and providing axial flexibility. This stent includes a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis, the spatial frequency of the wave associated with each of the bands being decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section; and a plurality of links for maintaining the bands in a tubular structure. The first and second regions have been further defined as the region that lies between the first and second ends and a set of circumferential links lying closest to the first end and second end.

In a further embodiment the widths of the sections of the bands, measured in a circumferential direction, are greater in the first and second end regions than in the intermediate section.

Brief Description of the Drawings

The foregoing aspects of the invention will be more readily understood by reference to the following detailed description, taken with the accompanying drawings, in which:

Figs 1 (a) and 1 (b) are side views of a stent having circumferentially disposed bands wherein the stent is in axially unbent and bent positions respectively, the latter showing protruding edges.

5 Figs 1 (c) and 1 (d) are side views of an axially flexible stent in accordance with the present invention wherein the stent is in unbent and bent positions respectively, the latter displaying an absence of protruding edges.

Fig. 2 is a side view of a portion of the stent of Figs. 1(c) and 1(d) showing the longitudinal bands, spaces, and inner radial measurements of bends in the bands being measured in inches.

10 Figs. 3 (a) and 3 (b) show a portion of the stent of Fig. 2 with two bands between two circumferential links (a) before expansion in the undeformed state; and (b) after expansion, in the deformed state.

Fig. 4 is a view along the length of a piece of cylindrical stent (ends not shown) prior to expansion showing the exterior surface of the cylinder of the stent and the characteristic
15 banding pattern.

Fig. 5 is an isometric view of a deflection plot where the stent of Fig. 2 is expanded to a larger diameter of 5mm.

Fig. 6 shows a two-dimensional layout of the stent of Fig. 4 to form a cylinder such that edge "A" meets edge "B", and illustrating the spring-like action provided in circumferential and
20 longitudinal directions.

Figure 7 shows a two dimensional layout of the stent. The ends are modified such that the length (L_A) is about 20% shorter than length (L_B) and the width of the band A is greater than the width of band B.

25 **Detailed Description of Specific Embodiments**

Improvements afforded by embodiments of the present invention include (a) increased flexibility in two planes of the non-expanded stent while maintaining radial strength and a high percentage open area after expansion; (b) even pressure on the expanding stent that ensures the consistent and continuous contact of expanded stent against artery wall; (c) avoidance of
30 protruding parts during bending; (d) removal of existing restrictions on maximum length of

stent; and reduction of any shortening effect during expansion of the stent.

In a preferred embodiment of the invention, an expandable cylindrical stent is provided having a fenestrated structure for placement in a blood vessel, duct or lumen to hold the vessel, duct or lumen open, more particularly for protecting a segment of artery from restenosis after angioplasty. The stent may be expanded circumferentially and maintained in an expanded configuration, that is circumferentially rigid. The stent is axially flexible and when flexed at a band, the stent avoids any externally protruding component parts. Figure 1 shows what happens to a stent, of a similar design to a preferred embodiment herein but utilizing instead a series of circumferentially disposed bands, when caused to bend in a manner that is likely encountered within a lumen of the body. A stent with a circumferential arrangement of bands (1) experiences an effect analogous to a series of box cars on a railway track. As the row of box cars proceeds around the bend, the corner of each car proceeding around the bend after the coupling is caused to protrude from the contour of the track. Similarly, the serpentine circumferential bands have protrusions (2) above the surface of the stent as the stent bends. In contrast, the novel design of the embodiment shown in Figs. 1 (c) and 1 (d) and Figure 7 in which the bands (3) are axially flexible and are arranged along the longitudinal axis, avoids the box car effect when the stent is bent, so the bent bands (4) do not protrude from the profile of the curve of the stent. Furthermore, any flaring at the ends of the stent that might occur with a stent having a uniform structure is substantially eliminated by introducing a modification at the ends of the stent. This modification comprises decreasing the spatial frequency and increasing the width of the corresponding bands in a circumferential direction (L_A and A) compared to that of the intermediate section. (L_B and B). Other modifications at the ends of the stent may include increasing the thickness of the wall of the stent and selective electropolishing. These modifications protect the artery and any plaque from abrasion that may be caused by the stent ends during insertion of the stent. The modification also may provide increased radio-opacity at the ends of the stent. Hence it may be possible to more accurately locate the stent once it is in place in the body.

The embodiment as shown in Figs. 2 and 6 has the unique advantage of possessing effective "springs" in both circumferential and longitudinal directions shown as items (5) and (6) respectively. These springs provide the stent with the flexibility necessary both to navigate

vessels in the body with reduced friction and to expand at the selected site in a manner that provides the final necessary expanded dimensions without undue force while retaining structural resilience of the expanded structure.

As shown in both Figs. 2, 4 and 6, each longitudinal band undulates through approximately two cycles before there is formed a circumferential link to an adjacent band. Prior to expansion, the wave associated with each of the bands may have approximately the same fundamental spatial frequency, and the bands are so disposed that the waves associated with them are spatially aligned, so as to be generally in phase with one another as shown in Fig. 6.

The aligned bands on the longitudinal axis are connected at a plurality of periodic locations, by a short circumferential link to an adjacent band. Consider a first common axial position such as shown by the line X-X in Fig. 4 and 6. Here an adjacent pair of bands is joined by circumferential link 7. Similarly other pairs of bands are also linked at this common axial position. At a second common axial position, shown in Fig. 6 by the line Y-Y, an adjacent pair of bands is joined by circumferential link 8. However, any given pair of bands that is linked at X-X is not linked at Y-Y and vice-versa. The X-X pattern of linkages repeats at the common axial position Z-Z. In general, there are thus two groups of common axial positions. In each of the axial positions of any one group are links between the same pairs of adjacent bands, and the groups alternate along the longitudinal axis of the embodiment. In this way, circumferential spring 5 and the longitudinal spring 6 are provided.

A feature of the expansion event is that the pattern of open space in the stent of the embodiment of Fig. 2 before expansion is different from the pattern of the stent after expansion.

In particular, in a preferred embodiment, the pattern of open space on the stent before expansion is serpentine, whereas after expansion, the pattern approaches a diamond shape (3a, 3b). In embodiments of the invention, expansion may be achieved using pressure from an expanding balloon or by other mechanical means.

In the course of expansion, as shown in Fig. 3, the wave shaped bands tend to become straighter. When the bands become straighter, they become stiffer and thereby withstand relatively high radial forces. Fig. 3 shows how radial expansion of the stent causes the fenestra to open up into a diamond shape with maximum stress being expended on the apices of the

diamond along the longitudinal axis. When finite element analyses including strain studies were performed on the stent, it was found that maximum strain was experienced on the bands and links and was below the maximum identified as necessary to maintain structural integrity.

5 The optimization of strain and "pop" pressure of the stent is achieved by creating as large a turn radius as possible in the wave associated with each band in the non-expanded stent while preserving a sufficient number of bands and links to preserve the structural integrity of the stent after expansion. The number of bands and the spatial frequency of the wave they describe on the longitudinal axis also affects the number of circumferential links. The circumferential links contribute structural integrity during application of radial force used in expansion of the
10 stent and in the maintenance of the expanded form.

The stent may be fabricated from many methods. For example, the stent may be fabricated from a hollow or formed stainless steel tube that may be cut out using lasers, electric discharge milling (EDM), chemical etching or other means. The stent is inserted into the body and placed at the desired site in an unexpanded form. In a preferred embodiment, expansion of
15 the stent is effected in a blood vessel by means of a balloon catheter, where the final diameter of the stent is a function of the diameter of the balloon catheter used.

In contrast to stents of the prior art, the stent of the invention can be made at any desired length, most preferably at a nominal 30mm length that can be extended or diminished by increments, for example 1.9mm increments.

20 It will be appreciated that a stent in accordance with the present invention may be embodied in a shape memory material, including, for example, an appropriate alloy of nickel and titanium, or stainless steel. In this embodiment after the stent has been formed, it may be compressed so as to occupy a space sufficiently small as to permit its insertion in a blood vessel or other tissue by insertion means, wherein the insertion means include a suitable catheter, or
25 flexible rod. On emerging from the catheter, the stent may be configured to expand into the desired configuration where the expansion is automatic or triggered by a change in pressure, temperature or electrical stimulation.

An embodiment of the improved stent has utility not only within blood vessels as described above but also in any tubular system of the body such as the bile ducts, the urinary system, the digestive tube, and the tubes of the reproductive system in both men and women.

continued on next page

What is claimed is:

1. A stent having first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis and providing axial flexibility, comprising:

5 a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis; and

a plurality of links for maintaining the bands in a tubular structure.

10 2. A stent according to claim 1, wherein each band is connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band.

3. A stent according to claim 1, wherein the wave associated with each of the bands has approximately the same fundamental spatial frequency for the intermediate section.

15 4. A stent according to claim 3, wherein the bands are so disposed that the waves associated with them are spatially aligned so as to be generally in phase with one another.

5. A stent according to claim 4, wherein the spatially aligned bands are connected, at a
20 plurality of periodic locations, by a short circumferential link to an adjacent band.

6. A stent according to claim 5, wherein, at each one of a first group of common axial positions, there is a circumferential link between each of a first set of adjacent pairs of bands.

25 7. A stent according to claim 5, wherein, at each one of a second group of common axial positions, there is a circumferential link between each of a second set of adjacent rows of bands, wherein, along the longitudinal axis, a common axial position occurs alternately in the first group and in the second group, and the first and second sets are selected so that a given band is linked to a neighboring band at only one of the first and second groups of common axial
30 positions.

8. A stent according to claim 2, wherein the spatial frequency of the wave associated with each of the bands, is decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section.

9. A stent according to claim 8, wherein the spatial frequency is decreased by about 20 % compared with the spatial frequency of the wave in the intermediate section.

10. A stent according to claim 8, wherein the first end region lies between the first end and a set of circumferential links lying closest to the first end and the second end region lies between the second end and a set of circumferential links lying closest to the second end.

11. A stent according to claim 8, wherein widths of corresponding sections of the bands, measured in a circumferential direction, are greater in the first and second end regions than in the intermediate section.

12. A stent according to claim 10, wherein widths of corresponding sections of the bands, measured in a circumferential direction, are greater in the first and second end regions than in the intermediate section.

13. A stent according to claim 1, wherein each band includes a terminus at each of the first and second ends and the adjacent pairs of bands are joined at their termini to form a closed loop.

14. A stent according to claim 8, wherein each band includes a terminus at each of the first and second ends and the adjacent pairs of bands are joined at their termini to form a closed loop.

15. A stent according to claim 9, wherein the first end region lies between the first end and a set of circumferential links lying closest to the first end and the second end region lies between the second end and a set of circumferential links lying closest to the second end.

5 16. A stent according to claim 15, wherein widths of corresponding sections of the bands, measured in a circumferential direction, are greater in the first and second end

17. A stent according to claim 7, wherein the spatial frequency of the wave associated with each of the bands, is decreased in a first end region lying proximate to the first end and a
10 second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section.

18. A stent having first and second ends with an intermediate section therebetween, the stent further having a longitudinal axis and providing axial flexibility, comprising:

15 a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave having a spatial frequency along a line segment parallel to the longitudinal axis; the spatial frequency of the wave associated with each of the bands being decreased in a first end region lying proximate to the first end and in a second end region lying proximate to the second end, in comparison to the spatial frequency of the wave in the intermediate section;
20 and

 a plurality of links for maintaining the bands in a tubular structure.

19. A stent according to claim 18, wherein widths of sections of the bands, measured in a circumferential direction, are greater in the first and second end regions than in the
25 intermediate section.

ABSTRACT

A stent with axial flexibility, in a preferred embodiment, has a longitudinal axis and comprises a plurality of longitudinally disposed bands, wherein each band defines a generally continuous wave along a line segment parallel to the longitudinal axis. A plurality of links maintains the bands in a tubular structure. In a further embodiment of the invention, each longitudinally disposed band of the stent is connected, at a plurality of periodic locations, by a short circumferential link to an adjacent band.

FIG. 1(a)

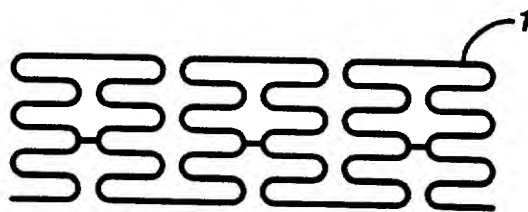


FIG. 1(b)

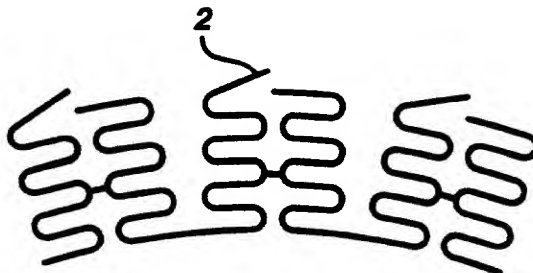


FIG. 1(c)

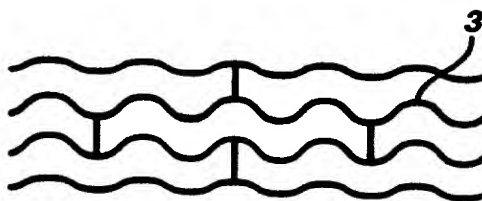


FIG. 1(d)

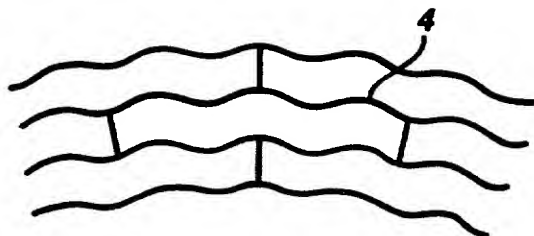


FIG. 2

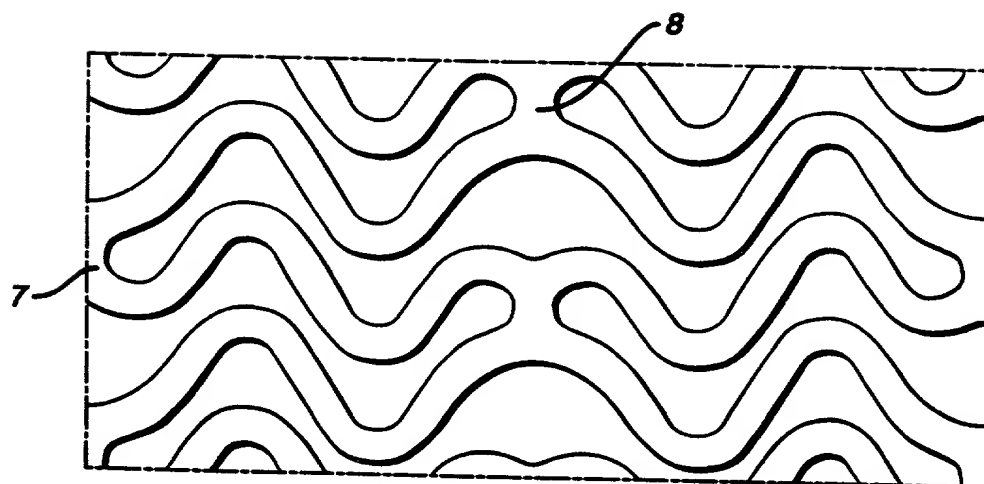


FIG. 3(a)

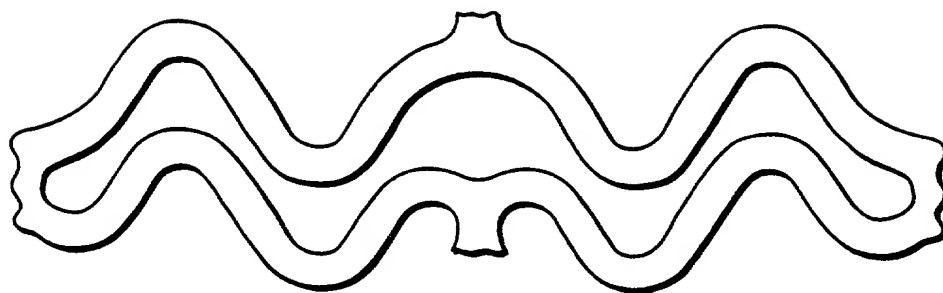


FIG. 3(b)

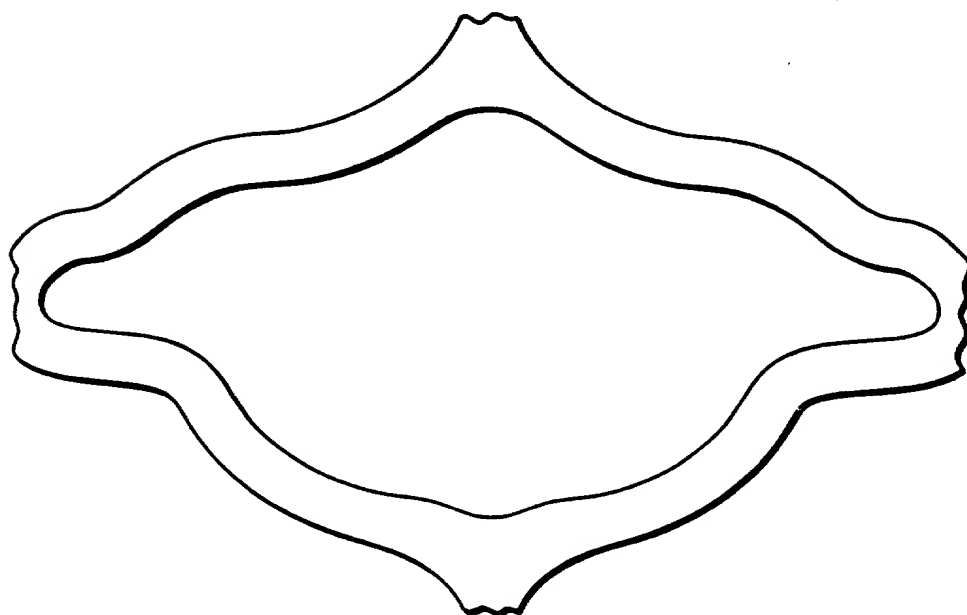


FIG. 4

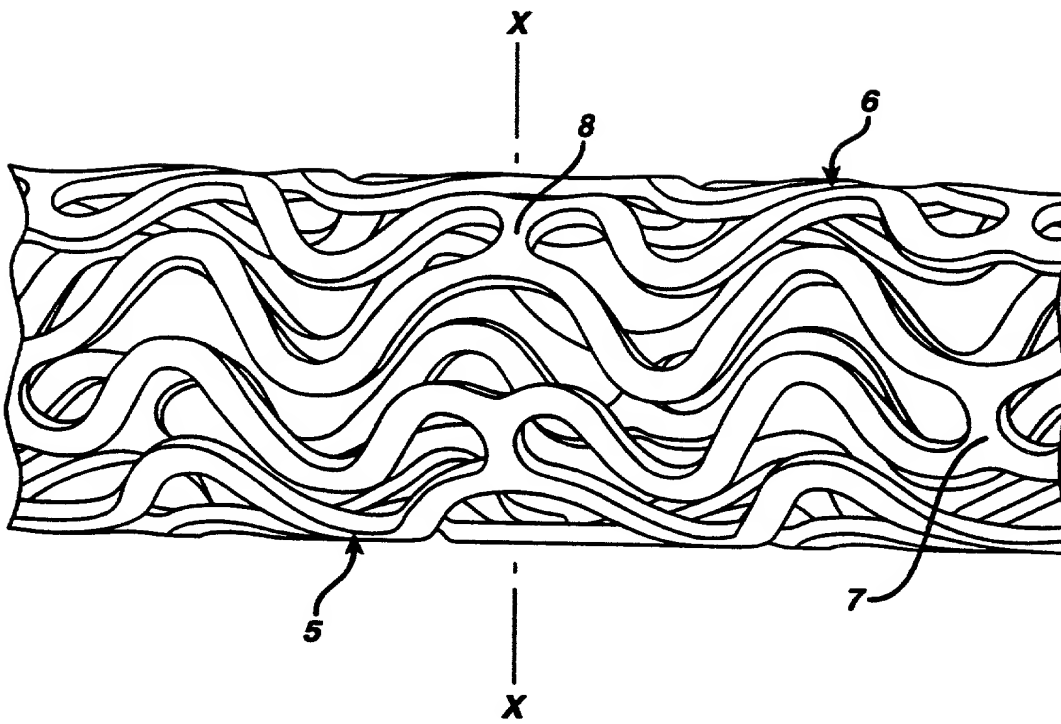


FIG. 5

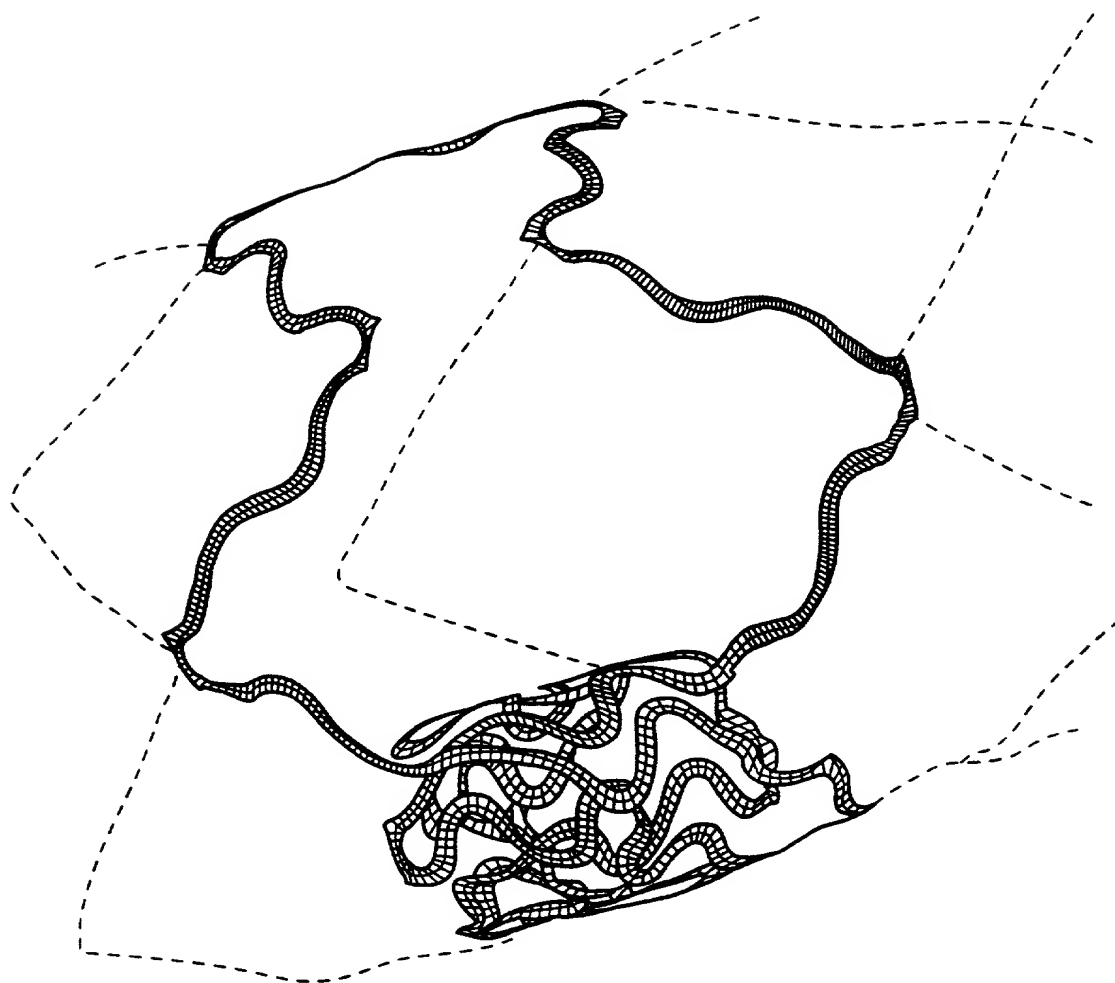


FIG. 6

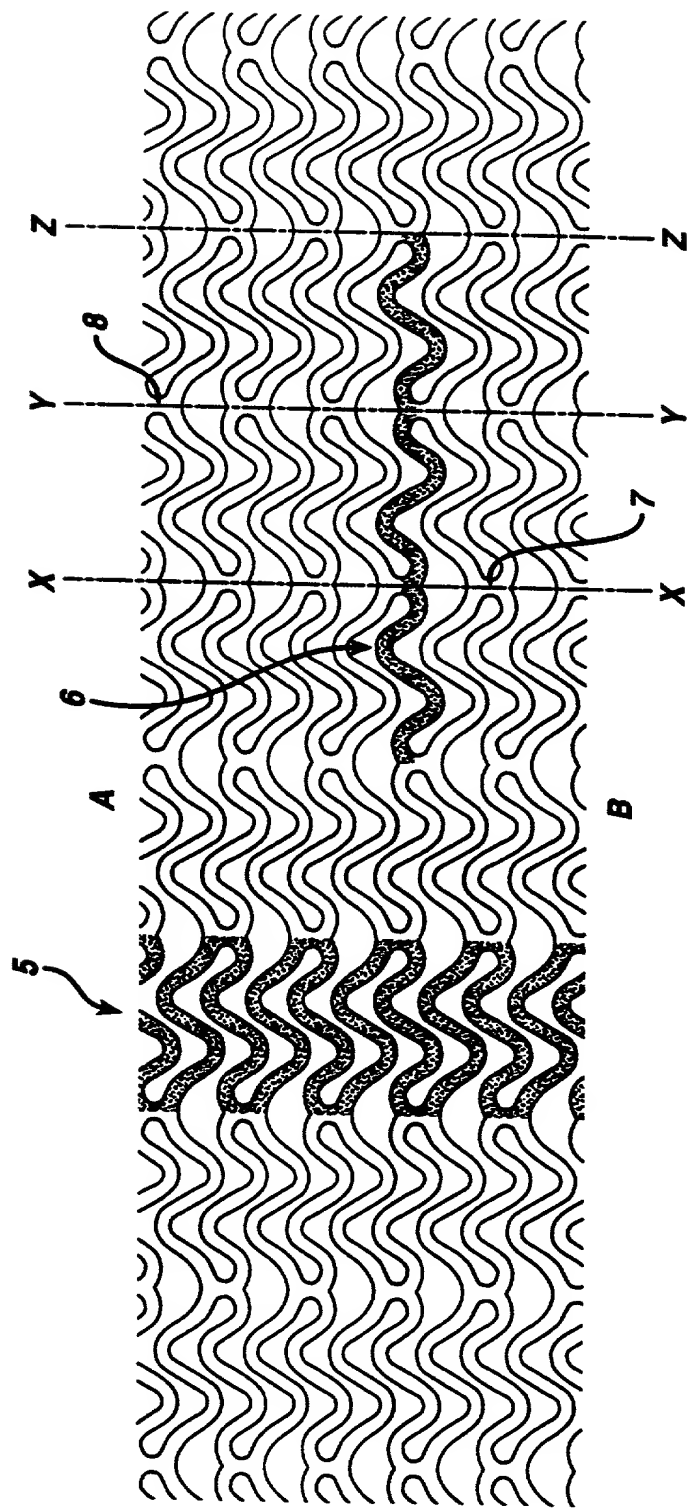
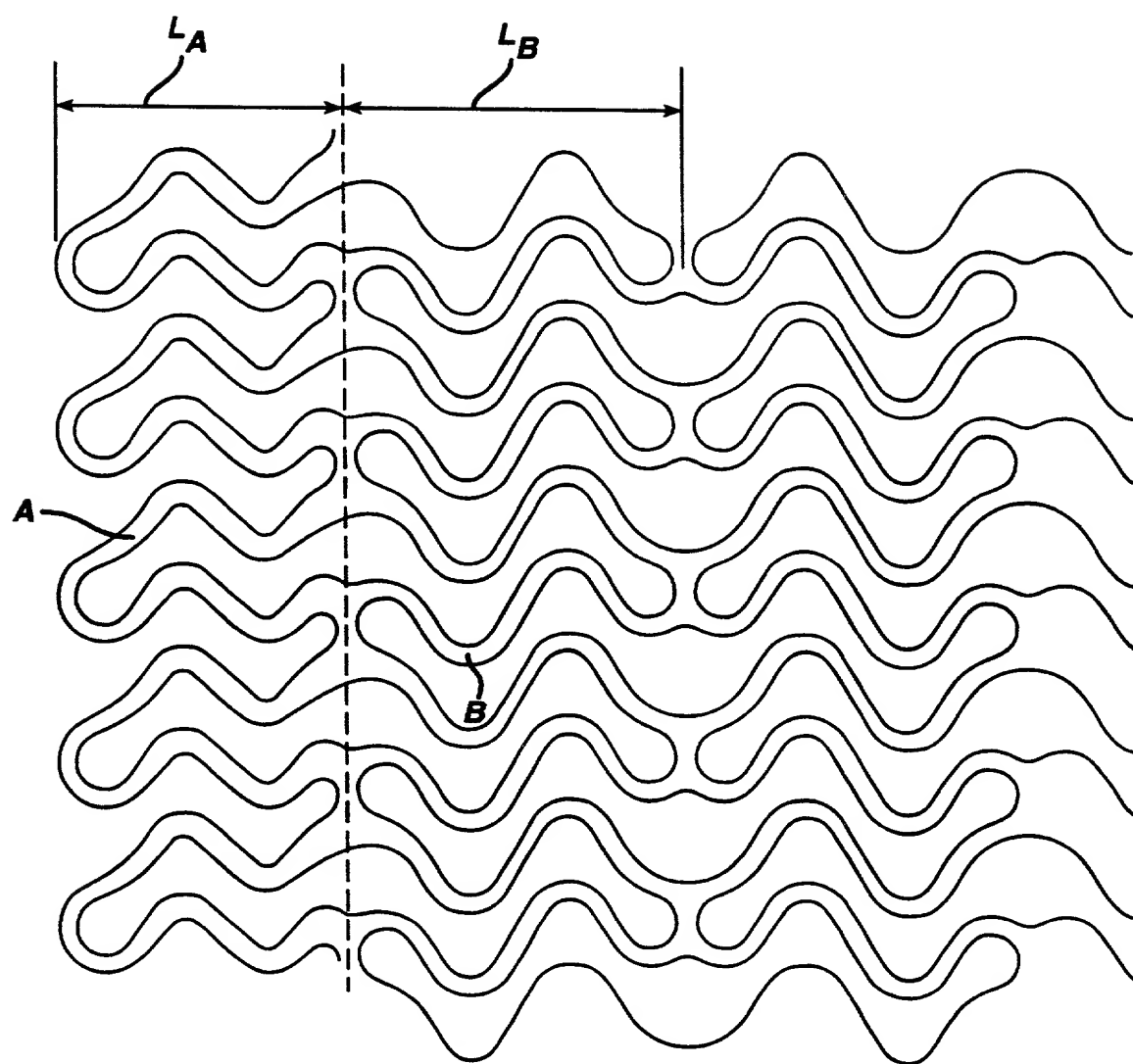


FIG. 7



DECLARATION AND POWER OF ATTORNEY

We, the below named inventors, hereby declare that:

Our residences, post office addresses, and citizenships are as stated below next to our respective names.

We believe we are the original, first, and joint inventors of the subject matter which is claimed and for which a patent is sought on the invention entitled **AXIALLY FLEXIBLE STENT**, the specification of which:

— is attached hereto.

X was filed on December 20, 1996 as serial number 08/770,236.

We hereby state that we have reviewed and understand the contents of the above identified specification, including the claims.

We acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, Section 1.56(a).

We hereby claim the benefit under 35 U.S.C. §119(e) of United States provisional applications 60/010,686 filed January 26, 1996; 60/017,479 filed April 26, 1996; 60/017,415 filed May 8, 1996; and 60/024,110 filed August 16, 1996.

We hereby appoint the following attorneys:

	<u>Registration No.</u>
Bruce D. Sunstein	27,234
Robert M. Asher	30,445
Timothy M. Murphy	33,198
Harriet M. Strimpel	37,008
Chinh H. Pham	39,329
Samuel J. Petuchowski	37,910

all of the firm BROMBERG & SUNSTEIN, to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

We request that all correspondence be directed to:

BROMBERG & SUNSTEIN
125 Summer Street, 11th Floor
Boston, MA 02110-1618

Attn: Harriet M. Strimpel, Ph.D.

and all telephone calls should be directed to:

Harriet M. Strimpel, Ph.D. (617) 443-9292

We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Larry B. Gray

Full name of **first** inventor

Larry

First name

B.

Middle initial

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Last name

Inventor's signature: Larry B. Gray

Date: 2/3/97

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Ann Eckert

Full name of **second** inventor

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Country of Citizenship: USA

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**IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE**

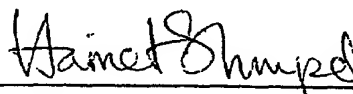
Applicant: Gray, et al. Atty Dkt: 1062/B40
Serial No: 08/770,236 Examiner: Lewis, W.
Date Filed: December 20, 1996 Date: March 13, 1998
Invention: AXIALLY FLEXIBLE STENT

ASSOCIATE POWER OF ATTORNEY

Please recognize Paul Coletti (Reg. No. 32,019) of Johnson & Johnson, One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933-7003 as associate attorney in the above mentioned application, with full power to prosecute said application, to make alterations and amendments therein, and to transact all business in the Patent and Trademark Office connected therewith.

Telephone calls should be made to Harriet M. Strimpel by dialing (617) 443-9292.

All written communications are to be addressed to Bromberg & Sunstein LLP, 125 Summer Street, 11th Floor, Boston, Massachusetts 02110-1618.



Harriet M. Strimpel
Agent for Applicant(s)
Reg. No. 37,008

Dated: March 13, 1998